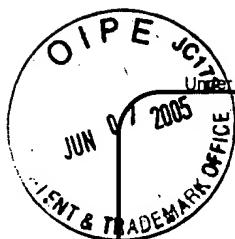


06-08-05 -

704624



PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

53

Application Number	09/807,647
Filing Date	April 16, 2001
First Named Inventor	S. Oi
Art Unit	1624
Examiner Name	B. Kifle
Attorney Docket Number	2560 USOP

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Return Postcard
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	<input type="checkbox"/> Appendix A (copy of previously submitted Information Disclosure Statement and copies of related transmittal papers)
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 500799.		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature	<i>Elaine M. Ramesh</i>		
Printed name	Elaine M. Ramesh		
Date	6/7/05	Reg. No.	43,032

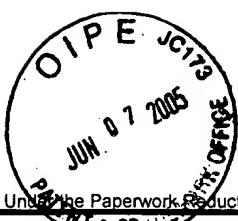
### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** **(\$)** 120.00

**Complete if Known**

Application Number	09/807,647
Filing Date	April 16, 2001
First Named Inventor	S. Oi
Examiner Name	B. Kifle
Art Unit	1624
Attorney Docket No.	2560 USOP

**METHOD OF PAYMENT (check all that apply)**

Check  Credit card  Money Order  Other  None

Deposit Account:

Deposit Account Number **500799**  
Deposit Account Name **Takeda Chemical Ind. Ltd.**

The Director is authorized to: (check all that apply)

Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) or any underpayment of fee(s)  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

**FEES CALCULATION****1. BASIC FILING FEE**

Large Entity	Small Entity	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1001	2001	790	395	Utility filing fee	
1002	2002	350	175	Design filing fee	
1003	2003	550	275	Plant filing fee	
1004	2004	790	395	Reissue filing fee	
1005	2005	160	80	Provisional filing fee	
<b>SUBTOTAL (1) (\$)</b>					

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims	Independent Claims	Multiple Dependent	Extra Claims	Fee from below	Fee Paid
			-20**	= <b>18</b>	= <b></b>
			- 3**	= <b>88</b>	= <b></b>
				<b>300</b>	<b></b>

Large Entity	Small Entity	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1202	2202	18	9	Claims in excess of 20	
1201	2201	88	44	Independent claims in excess of 3	
1203	2203	300	150	Multiple dependent claim, if not paid	
1204	2204	88	44	** Reissue independent claims over original patent	
1205	2205	18	9	** Reissue claims in excess of 20 and over original patent	
<b>SUBTOTAL (2) (\$)</b>					

\*or number previously paid, if greater; For Reissues, see above

**FEES CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity	Small Entity
--------------	--------------

Fee Code (\$)	Fee (\$)	Fee Code (\$)	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	120
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3) (\$)** 120.00**SUBMITTED BY**

(Complete if applicable)

Name (Print/Type)	Elaine M. Ramesh, Ph.D., JD	Registration No. (Attorney/Agent)	43,032	Telephone	847-383-3391	
Signature	<i>Elaine M. Ramesh</i>				Date	6/7/05

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Express Mailing # 21504904619 US*  
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



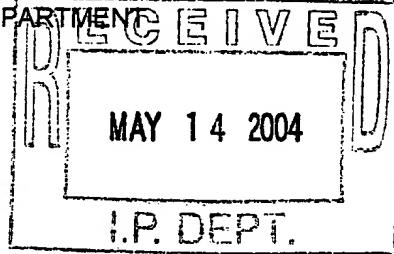
UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/807,647	Satoru Oi	2560USOP

23115

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.  
 INTELLECTUAL PROPERTY DEPARTMENT  
 475 HALF DAY ROAD  
 SUITE 500  
 LINCOLNSHIRE, IL 60069



INTERNATIONAL APPLICATION NO.

PCT/JP99/05754

I.A. FILING DATE	PRIORITY DATE
10/19/1999	10/20/1998

CONFIRMATION NO. 2246  
 371 ACCEPTANCE LETTER



\*OC000000012555359\*

Date Mailed: 05/10/2004

**NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495**

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

04/16/2001

DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and  
 (c)(4) REQUIREMENTS

06/29/2001

DATE OF COMPLETION OF ALL 35 U.S.C. 371  
 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE "FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 04/16/2001
- Copy of the International Search Report filed on 04/16/2001
- Copy of IPE Report filed on 04/16/2001
- Biochemical Sequence Diskette filed on 04/21/2004
- Oath or Declaration filed on 04/16/2001
- Biochemical Sequence Listing filed on 04/21/2004
- Copy of references cited in ISR filed on 04/16/2001
- U.S. Basic National Fees filed on 04/16/2001
- Priority Documents filed on 04/21/2004

U.S. Patent Application Serial No. 09/807,647

---

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

---

KAYA L LEWIS BALTIMORE  
Telephone: (703) 305-3695

PART 1 - ATTORNEY/APPLICANT COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)

U.S. Patent Application Serial No. 09/1807,647



**POST OFFICE  
TO ADDRESSEE**



EL 784119258 US



**POST OFFICE  
TO ADDRESSEE**



EL 784119258 US

**Customer Copy**  
Label 11-F August 2000

Label 11-F August 2000

11-F  
12

<b>ORIGIN (POSTAL USE ONLY)</b>		
ZIP Code 60069	Day of Delivery <input checked="" type="checkbox"/> Next <input type="checkbox"/> Second	Flat Rate Envelope <input type="checkbox"/>
Item In 4/16/01	Postage \$ 27.30	
Mo. Day Year 17 00	12 Noon <input type="checkbox"/> 3 PM <input type="checkbox"/>	Return Receipt Fee <input type="checkbox"/>
Int'l Alpha Country Code US	2nd Day <input type="checkbox"/> 3rd Day <input type="checkbox"/>	COD Fee <input type="checkbox"/>
AM PM 8:00 AM	Int'l Alpha Country Code US	Insurance Fee <input type="checkbox"/>
lbs. 0.3	Acceptance Clerk Initials DM	Total Postage & Fees \$ 27.30
<input type="checkbox"/> Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday		

**SEE REVERSE SIDE FOR  
SERVICE GUARANTEE AND LIMITS  
ON INSURANCE COVERAGE**

**WAIVER OF SIGNATURE** (Domestic Only): Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.

NO DELIVERY  Weekend  Holiday  Customer Signature

Federal Agency Acct. No. or

Postal Service Acct. No.

**CUSTOMER USE ONLY**

**METHOD OF PAYMENT:**

Press Mail Corporate Acct. No.

600672

PHONE 847-383-3372

MARK CHAO  
TAKEDA PHARMACEUTICALS  
AMERICA INC  
475 HALF DAY RD STE 500  
LINCOLNSHIRE IL 60069-2935

Docket #2560 USOP

**TO: (PLEASE PRINT)**

PHONE \_\_\_\_\_

BOX PCT  
COMMISSIONER OF  
PATENTS AND TRADEMARKS  
WASHINGTON DC 20231-0001

FOR PICKUP OR TRACKING CALL 1-800-222-1811 [www.usps.com](http://www.usps.com)



**UNITED STATES  
POSTAL SERVICE**  
\*\*\*\*\* WELCOME TO \*\*\*\*\*  
LINCOLNSHIRE PO  
LINCOLNSHIRE, IL 60069-9998  
04/16/01 04:41PM

Store USPS Trans 165  
Wkstn sys5002 Cashier KK14SH  
Cashier's Name Greg  
Stock Unit Id GREGSSA  
PO Phone Number 847-634-3260

1. Exp. Mail PO-ADD 0.00  
Destination: 20231  
Weight: 51b 4.30oz  
Postage Type: None  
Total Cost: 27.30  
Base Rate: 27.30  
Label#: EL784119258US  
Corporate Acct.: 600672  
Amount Charged: 27.30

Subtotal	0.00
Total	0.00

Number of Items Sold: 1

Thank You  
Please come again!

U.S. Patent Application Series No. 09/1807,6047

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371ATTY. Y'S DOCKET NUMBER  
2560US0P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO. PCT/JP99/05754	INTERNATIONAL FILING DATE October 19, 1999	PRIORITY DATE CLAIMED October 20, 1998
TITLE OF INVENTION 1,5-Benzodiazepine Compounds, Their Production and Use		
APPLICANT(S) FOR DO/EO/US Satoru Oi et al.		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3.  This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4.  A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5.  A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a.  is transmitted herewith (required only if not transmitted by the International Bureau).
  - b.  has been transmitted by the International Bureau.
  - c.  is not required, as the application was filed in the United States Receiving Office (RO/US).
6.  A translation of the International Application into English (35 U.S.C. 371(c)(2)). \*
7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a.  are transmitted herewith (required only if not transmitted by the International Bureau).
  - b.  have been transmitted by the International Bureau.
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
8.  A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.  An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10.  A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11. to 16. below concern document(s) or information included:

11.  An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12.  An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13.  A **FIRST** preliminary amendment.
- A **SECOND** or **SUBSEQUENT** preliminary amendment.
14.  A substitute specification.
15.  A change of power of attorney and/or address letter.
16.  Other items or information:
  - 1) Sequence Listing (Paper & Computer-readable copies)
  - 2) Sequence Listing Statement

\* This includes specification 221 total pages, including  
Claims 1-18 (9 pgs), Abstract (1 pg), and Sequence  
listing (4 pgs).

Express Mail Label # : EL 784119258US Docket # : 2560US0P  
Applicants : Satoru OI et al. Date : 4/16/01

Title : "1,5-Benzodiazepine Compounds, Their Production and Use"

Kindly acknowledge receipt of the accompanying:

- 1) This PTO Return Receipt Postcard
- 2) Transmittal letter (2 pgs X 2)
- 3) A Translation of the International Application into English  
[This includes Specification 221 total pages, including Claims 1-18 (9 pgs.),  
Abstract (1 pg.), and Sequence Listing (4 pgs.)]
- 4) Executed Declaration
- 5) Information Disclosure Statement with PTO form 1449, and copies of  
IDS citations (6), and the International Search Report
- 6) Executed Assignment and assignment cover sheet (and one copy of the  
cover sheet)
- 7) Sequence Listing Statement
- 8) Sequence Listing (Paper & Computer-readable copies)

**09/807647**

Express Mail Label # : EL 784119258US Docket # : 2560US0P  
Applicants : Satoru OI et al. Date : 4/16/01

Title : "1,5-Benzodiazepine Compounds, Their Production and Use"

Kindly acknowledge receipt of the accompanying:

- 1) This PTO Return Receipt Postcard
- 2) Transmittal letter (2 pgs X 2)
- 3) A Translation of the International Application into English  
[This includes Specification 221 total pages, including Claims 1-18 (9 pgs.),  
Abstract (1 pg.), and Sequence Listing (4 pgs.)]
- 4) Executed Declaration
- 5) Information Disclosure Statement with PTO form 1449, and copies of  
IDS citations (6), and the International Search Report
- 6) Executed Assignment and assignment cover sheet (and one copy of the  
cover sheet)
- 7) Sequence Listing Statement
- 8) Sequence Listing (Paper & Computer-readable copies)

**JC07 Rec'd PCT/PTO 16 APR 2001**

U.S. Patent Application Serial No. 09/807,647

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: tba  
Filed: tba  
1<sup>st</sup> Inventor: Satoru OI  
For: 1,5-Benzodiazepine Compounds, Their Production and Use  
Atty. Dkt. No. 2560 USOP

Art Unit: tba  
Examiner: tba  
Allowed:  
Batch:  
Paper No.:

**CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10**

**USPS EXPRESS MAIL LABEL. No. EL 784119258 US**

**DATE IN: April 16, 2001**

**Itemized Papers/Items:**

1. This certificate and a Return Receipt Postcard (2 pgs.)
2. Transmittal Letter for Filing under 35 USC 371 (2 pgs. X 2)
3. English Translation of the International Application as filed in Japanese [This includes Specification 221 total pages, including Claims 1-18 (9 pgs.), Abstract (1 pg.) and Sequence Listing (4 pgs.)]
4. Executed Declaration/Power of Attorney (4 pgs.)
5. Information Disclosure Statement (2 pgs.) with PTO form 1449 (1 pg.), and copies of IDS citations (6), and the International Search Report (2 pgs.)
6. Executed Assignment (2 pgs.) and assignment cover sheet (1 pg. X 2)
7. Sequence Listing Statement (1 pg.)
8. Sequence Listing (Paper & Computer-readable copies) (2 pgs.)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

BOX PCT  
Commissioner for Patents  
Washington, D.C. 20231.

on this date, 4/16/01.

*Gail L. Winokur*

Dated: Gail L. Winokur

EL784119258US

U.S. Patent Application Serial No. 09/1807,647